SEP 12 2003

K032588

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510(K) Summary

Disc-O-Tech Medical Technologies, Ltd.

Fixion® Intramedullary Nailing System; Fixion® Interlocking Intramedullary Nailing System; Fixion® Interlocking Proximal Femoral Intramedullary Nailing System

Company Name

Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot St., Herzliya
Israel, 46728

Submitter's Name and Contact Person

Yael Rubin
Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot St., Herzliya
Israel, 46728
Tel: +972 9 9511511
Fax: +972 9 9548939

Date Prepared

August 2003

Trade/Proprietary Name

Fixion® Intramedullary Nailing System; Fixion® Interlocking Intramedullary Nailing System; Fixion® Interlocking Proximal Femoral Intramedullary Nailing System;

Classification Name

Intramedullary Fixation Rod
21 CFR § 888.3020
Class II

Predicate Devices

1. Fixion Intramedullary Nailing System (K990717, K003212, K003215, K010901, K021324, K023437) by Disc-O-Tech.
2. Fixion Interlocking Intramedullary Nailing System (K002783, K013449, K023437)

by Disc-O-Tech.

3. Fixion Interlocking Proximal Femoral Intramedullary Nailing System (K010988, K012967, K023437) by Disc-O-Tech.
4. Unreamed Tibial Nail (K914453), by Synthes.
5. Universal Femoral Nail (K914371), by Synthes.

Performance Standards

The following standards were used:

1. The Fixion Intramedullary Nailing Systems Nails and Hip Peg are manufactured from Stainless Steel, which meets the requirements of ASTM F 138 (UNS31673)/ ISO 5832-1, and from Stainless Steel, which meets the requirements of ASTM F 1314 (UNS S20910).
2. The Fixion Intramedullary Nailing Systems are designed to meet the requirements of ASTM F 565 – Standard Practice for Care and Handling of Orthopedic Implants and Instruments.

Intended Use

Femur:

- ✓ fractures in the femur shaft, proximal femoral fractures, and combinations of these fractures;
- ✓ proximal femoral fractures including stable and unstable pertrochanteric, intertrochanteric, and subtrochanteric (with and without break-off of the minor trochanter), high subtrochanteric fractures and combinations of these fractures;
- ✓ use in osteotomy, nonunions and malunions, bone reconstruction following tumor resection, grafting and pathological fractures, and revision procedures in the femur;
- ✓ mid shaft fractures in the femur (5 cm below the surgical neck to 5 cm proximal to the distal end of the medullar canal);
- ✓ comminuted shaft fractures;
- ✓ fixation of short distal or proximal fragments

Tibia:

- ✓ diaphyseal shaft fractures in the tibia;
- ✓ comminuted shaft fractures;
- ✓ fixation of short distal or proximal fragments

Humerus:

- ✓ diaphyseal shaft fractures in the humerus;
- ✓ comminuted shaft fractures;
- ✓ fixation of short distal or proximal fragments

Substantial Equivalence

The modified Fixion Intramedullary Nailing Systems have the following similarities to those that previously received 510(k) concurrence:

- ✓ Have the same intended use
- ✓ Have the same operating principles
- ✓ Incorporate the same design principles
- ✓ Incorporate either the same or similar materials
- ✓ Have the same packaging and undergo the same sterilization processes, using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2003

Mr. Yael Rubin
Director of Regulatory Affairs
Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot St.
Herzliya, Israel 46728

Re: K032588
Trade/Device Names: Fixion® Intramedullary Nailing System,
Fixion® Interlocking Intramedullary Nailing System,
Fixion® Interlocking Proximal Femoral Inramedullary Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: August 20, 2003
Received: August 22, 2003

Dear Mr. Rubin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K032588

Device Name:
Fixion® Intramedullary Nailing System
Fixion® Interlocking Intramedullary Nailing System
Fixion® Interlocking Proximal Femoral Intramedullary Nailing System

Indication for Use: These devices are indicated for the following:

Femur:
- fractures in the femur shaft, proximal femoral fractures, and combinations of these fractures;
- proximal femoral fractures including stable and unstable pertrochanteric, intertrochanteric, and subtrochanteric (with and without break-off of the minor trochanter), high subtrochanteric fractures and combinations of these fractures;
- use in osteotomy, nonunions and malunions, bone reconstruction following tumor resection, grafting and pathological fractures, and revision procedures in the femur;
- mid shaft fractures in the femur (5 cm below the surgical neck to 5 cm proximal to the distal end of the medullar canal);
- comminuted shaft fractures;
- fixation of short distal or proximal fragments

Tibia:
- diaphyseal shaft fractures in the tibia;
- comminuted shaft fractures;
- fixation of short distal or proximal fragments

Humerus:
- diaphyseal shaft fractures in the humerus;
- comminuted shaft fractures;
- fixation of short distal or proximal fragments

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use _____
(per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032588